**RESERVED**

**Writ Petition no.427 (M/B) OF 2002**

M/s Poddar Pharmaceutical Ltd.
And others ---------- Petitioners

Versus

State of Uttaranchal
And others ---------- Respondents

**Hon'ble Irshad Hussain, J.**
**Hon'ble M.M. Ghildiyal, J.**

**(Delivered by Hon'ble M.M. Ghildiyal, J.**

By means of this writ petition the petitioners have prayed to quash the condition no.2 mentioned in the government order dated 13.9.2001 and condition no.6 of tender form, which requires the tenderer to attach along with the tender form a certificate of Director General Quality Assurance (Defence Ministry) certificate or Word Health Organization Goods Manufacturing Practice Certificate.

Brief facts of the case are that the petitioners were issued license by the respondents for manufacturing and sale of drugs. The said license was issued to the petitioners by the State of Uttar Pradesh and after creation of the State of Uttaranchal the same has been renewed by the State of Uttaranchal. Thus the petitioners were having valid license on the relevant date. Under Rule 71 and 76 of the Drugs and Cosmetics Rules 1945 a certificate was also issued to the petitioners known as Goods Manufacturing Practice Certificate (hereinafter referred to as G.M.P.) by the licensing authority of Uttaranchal and the said certificate was also valid on the relevant date. Further a certificate was also issued by the respondents for 'no conviction', which means that the drugs manufactured by the petitioners are of good quality and the petitioners were never implicated in any offence under the Drugs and Cosmetics Act, 1945.

Apart from these certificates, certificate known as Marketing Standing Certificate was also issued by the drugs licensing controlling authority, Uttaranchal.

The respondent no.1 issued a government order with regard to drugs to be purchased in the government hospitals, dispensaries and government institutions of the State of Uttaranchal and in the aforesaid order a condition was imposed that the drugs are to be purchased from the firms which are having Director General Quality Assurance (Defence Ministry) (for the short- D.G. Q.A) certificate or Word Health Organization Goods Manufacturing Practice Certificate (hereinafter referred to "WHO GMP') and only the firms which are having the aforesaid certificates would be legible to participate in tender process for supplying the drugs to government hospitals, dispensaries and government institutions of the State of Uttaranchal on rate contract. The petitioners who were having necessary license and certificates issued by the drugs controlling authority, Uttaranchal made a representation before the respondents that the condition laid down in the aforesaid government order is arbitrary and as such the same may be deleted from the said government order dated 13.9.2001. However, the respondents without considering the representation of the petitioners for deleting the condition of DGQA certificate and WHO GMP certificate floated a tender notice for supply to drugs to the government departments on rate contract basis and the conditions aforesaid, which were totally irrelevant and arbitrary, were laid down in the tender notice. Aggrieved with this, the petitioners have challenged the aforesaid conditions by means of this writ petition.

Heard Sri Rajendra Dobhal learned counsel for the petitioners and learned standing counsel for the respondents.

The petitioners have submitted that the petitioner no.2 approached on 18.4.2002 to Joint Director, Central Drugs Standard Control Organization (North Zone) who is a competent authority to recommend for issuance of WHO GMP certificate to the firms and the Joint Drugs Controller (India) Government of India, vide letter dated 8.5.2002 informed the petitioner no.2 that the certificate of WHO GMP is required only for export purpose and not for local marketing and since the petitioner no.2 is not engaged with the business of export of medicines he cannot be issued WHO GMP certificate. So far as DGQA certificate is concerned the same is required to be obtained by the firm, which supplies medicines to defence. The petitioners who have

valid license issued by the respondents for manufacturing and sale of drugs and also have valid GMP certificate issued by the competent authority under rules 71 and 76 of Drugs and Cosmetics Rules 1945 and are also in possession of 'no conviction" as well as Marketing Standing Certificate issued by the licensing and controlling authority, Uttaranchal have been deprived to participate in the process of tender floated by the State of Uttaranchal because of arbitrary conditions imposed therein.

Learned counsel for the petitioners has placed reliance on the judgment of Apex Court in the case of **Monarch Infrastructure (P) Ltd Vs. Commissioner, Ulhasnagar, Municipal Corporation and others, reported in (2000) 5 Supreme Court Cases 287.**

In the aforesaid case Municipal Corporation issued a notice inviting tender for appointment of agent for octroi subject to the terms and conditions set forth therein. One of the conditions of eligibility deleted after the expiry of the time limit for submission of tender but before award of contract thereof. The contract was awarded to a tenderer who at the time of submission of tender did not satisfy the condition, which was deleted. Hon'ble High Court set aside the award of contract. The said order was challenged before the Apex Court. The Apex Court in paragraphs no.11 and 12 has held as under:-

> "11.Broadly stated, the courts would not interfere with the matter of administrative action or changes made therein, unless the Government's action is arbitrary or discriminatory or the policy adopted has no nexus with the object it seeks to achieve or is mala fide.
> 12. If we bear these principles in mind, the High Court is justified in setting aside the award of contract in favour of Monarch Infrastructure (P) Ltd. Because it had not fulfilled the conditions relating to clause 6 (d) of the Tender Notice but the same was deleted subsequent to the last date of acceptance of the tenders. If that is so, the arguments advanced on behalf of Konark Infrastructure (P) Ltd. In regard to the allegation of mala fides of the Commissioner of the Municipal Corporation in showing special favour to Monarch Infrastructure (P) Ltd, or the other contentions raised in the High Court and reiterated before us are insignificant because the High Court had set aside the award made in favour of Monarch Infrastructure (P) Ltd. The only question therefore remaining is whether any contract should have been awarded in favour of Konark Infrastructure (P) Ltd. The High Court had taken the view that if a term of the tender having been deleted after the players entered into the arena it is like changing the rules of the game after it had begun and, therefore, if the Government

> or the Municipal Corporation was free to alter the conditions fresh process of tender was the only alternative permissible. Therefore, we find that the course adopted by the High Court in the circumstances is justified because by reason of deletion of a particular condition a wider net will be permissible and a larger participation or more attractive bids could be offered."

In the present case though the condition was itself imposed alongwith tender form but in view of the principle laid down by the Apex Court that the judicial review of such tender is permissible where the court found arbitrariness in the tender process.

The petitioners have stated that the condition laid down in the tender that only those persons can participate who are having either DGQA certificate or WHO GMP certificate is arbitrary and unreasonable. In view of the fact that WHO GMP certificate is required by the firms who intend to export the medicines. Further DGQA certificate is required when the firm is engaged to supply medicines to defence department. The petitioners are neither exporting nor supplying the medicines to the defence department and for manufacturing and sale of drugs license by the controlling authority of the State has already been granted to the petitioners. The petitioners have already been issued GMP certificate by the licensing authority of Uttaranchal under sections 71 and 76 of the Drugs and Cosmetics Rules 1945. Apart from the above certificates they have already been issued no conviction certificate as well as Marketing Standing Certificate. Thus, the condition imposed by the respondents that the drugs shall be purchased from the firms who are not having DGQA certificate or WHO GMP certificate was totally irrelevant and arbitrary.

Learned counsel for the petitioner have submitted that no firm in Uttaranchal is having WHO GMP/DGQA certificate and this condition has been imposed just to favour certain firms. The petitioners can sell their medicines in the open market from where any person can purchase and use the same because the petitioners are having necessary license and certificate to that effect but they have been deprived to sell their medicines to the government hospitals and dispensaries from where the said medicines will also be distributed to the public and as such the action of the respondents is wholly arbitrary. From the certificate issued by the Government itself it is

clear that the medicines manufactured by the petitioners are of standard according to norms and that is why have been issued licenses for manufacture and sale of medicines and the petitioners are selling their medicines in the open market. It is being used by the general public. The respondent cannot say nor they have said that the medicines of the petitioners are of sub standard and cannot be permitted to be used by the general public through the government hospitals and dispensaries etc.

Learned Standing Counsel has admitted that the petitioners firms are having license to manufacture drugs by the State Drugs Licensing authority Uttaranchal in compliance of the notification under rules 69 and 75 of the Drugs & Cosmetics Rules 1945. The learned counsel for the respondents has submitted that the GMPs were incorporated in Rules 71, 74, 76 and 78 in the year 1988 with a view to gradually improve the manufacturing work by process of issuing suggestions but failing to educate the drug manufactures through self-discipline the Central Government has modified the GMP vide notification dated 11.12.2001 making all provisions mandatory for compliance and also notified in general that all such industries who are not interested to improve be not allowed to function beyond 31.12.2003. The said changes were communicated to the petitioners vide order dated 26.8.2002. The learned counsel for the respondents further submitted that the petitioners manufacturing unit still require many changes in terms of buildings, machines, keeping of fool proof records and conducting contaminant free drug production. If the petitioners are not producing contaminant free drugs the license should not have been issued to the petitioners and even after issuing of license the controlling authority has sufficient power to take action against the petitioners. On the contrary the government has issued no conviction certificate.

Learned Standing Counsel has further submitted that it is not correct that no unit in Uttaranchal is having certificate of WHO GMP. He has drawn our attention to annexure 5 to the counter affidavit which shows that M/s Windlodge Biotech Limited, Mohabewala, Dehradun has been issued WHO GMP certificate for 38 medicines. The learned counsel for the petitioners has drawn our attention to the letter dated 8.5.2002 issued by the Joint Drugs Controller (India) to the petitioner no.2 informing that WHO GMP

Certificate are issued for production of medicines for International Commerce (Export) whenever the importing countries desire and not for local marketing. Thus, it is clear from the letter that the certificate of WHO GMP is required only for the purpose of export.

Learned S.C. has placed reliance on the judgment in the case of **Sheo Kumar v. State of U.P. and others, reported in AIR 1978 Allahabad 386.** In the aforesaid case constitutional virus of section 37 A of the Excise Act, 1910 and of the notification issued therein on March 30 and 31, 1978 were challenged. By the aforesaid notifications the Government had introduced total prohibition of Tari in the State and partial prohibition in respect of country-made and foreign liquors. The court while allowing the writ petition held that section 37 A was violative of Article 14 of the Constitution of India and was a nullity, the notification issued by the State Government there under cannot be sustained. The respondents cannot take any help of the above Judgment.

Learned Standing Counsel has further placed reliance on the judgment of Apex Court in the case of **W.B. State Electricity Board Vs. Patel Engineering Company Limited and others, reported in (2001) 2 Supreme Court Cases 451** wherein the Apex Court has held that in a government tender permitting the bidder to correct error in his bid documents which are not merely clerical or mechanical when such corrections not permissible under rules governing the process of tender held, was not within the scope of judicial review. The respondents cannot take any benefit of this authority also because in this case the company who had submitted lowest bid informed the Board that (a) “repetitive systematic typographical transmission failure” had occurred in their bid documents and requested that it be rectified. The facts of the present case are totally different and it is well settled law that in case of arbitrariness in government contracts the scope of judicial review is always there. The controversy in this case is that though the petitioners were having valid license for manufacturing and sale of drugs issued under rules 71 and 76 of the Drugs & Cosmetics Rules, 1945, GMP, no conviction certificate and Marketing Standing Certificate was issued by the competent authority, yet they have not been permitted to participate in the tender process on the ground that

they were not having WHO GMP or DG QA certificate though WHO GMP certificate is required for export purposes and DGQA certificate is required when the firm is engaged for supply of medicines to defence department. It cannot be disputed that this is a competition bidding which postulate keen competitive and high efficiency. The degree of care required in such a bidding is greater than in ordinary local bids for small works. It is also essential to maintain sanctity and integrity of process of tender and also the public interest but at the same time it will have to be seen that the government of Uttaranchal has issued all the necessary certificates which permit the petitioners to manufacture and sell their medicines in open market from where the general public may purchase and use the same. In this eventuality the State Government cannot deprive the petitioners to participate in the tender process for supply of medicines to the government hospitals and dispensaries etc on rate contract, which will be ultimately distributed to the general public. Thus the policy of the government to impose such condition is unfair, unreasonable and arbitrary to that effect.

For the reasons stated above the writ petition is allowed and the condition no.2 mentioned in the government order dated 13.9.2001 and condition no.6 of tender form are quashed. No order as to costs.

**(Irshad Hussain, J.)** **(M.M. Ghildiyal, J.)**

May 24, 2003
MPS